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LAWRENCE BRADFORD

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

LAWRENCE BRADFORD, on behalf of himself and all others similarly situated, Plaintiff, v. ANTHEM, INC.; ANTHEM UM SERVICES, INC., Defendants.	Case No.: 2:17-cv-5098 **CLASS ACTION** **COMPLAINT FOR BENEFITS, DETERMINATION OF RIGHTS AND BREACH OF FIDUCIARY DUTY UNDER ERISA**

Plaintiff, Lawrence Bradford, on behalf of himself and all others similarly situated, herein sets forth the allegations of his Complaint against Defendants Anthem, Inc. and Anthem UM Services, Inc. (Collectively, "Defendants").

INTRODUCTION

1. Anthem, Inc. ("Anthem") is "one of the largest health benefit companies in terms of medical membership in the United States, serving 39.9 million medical members through [its] affiliated health plans as of December 31, 2016."[1] Anthem owns "Blue" organizations in California and many other states.[2] Through its wholly-owned subsidiaries, including Defendant Anthem UM Services, Inc. ("Anthem UM"), Anthem acts as a fully integrated company that is in the business of insuring and administering health insurance plans, most of which are employer-sponsored and governed by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001, *et seq*. ("Anthem Plans").

2. With respect to all Anthem Plans, Anthem UM serves as the claims administrator, responsible for determining whether claims are covered under Anthem Plans (both fully insured and self-insured) and effectuating any resulting benefit payment. Anthem aids Anthem UM in its administrative duties by, among other things, participating with Anthem UM in the development of coverage guidelines called Medical Policies, collaborating with Anthem UM on the types of claims that will be approved or denied, and assisting Anthem UM in carrying out its various other administrative duties. As such, Defendants have acted as ERISA fiduciaries with respect to all Anthem Plans, including Plaintiff Lawrence Bradford's plan.

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[1] Anthem's 2016 10-K, p. 3.

[2] Those states are Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri (excluding 30 counties in the Kansas City area), Nevada, New Hampshire, New York, Ohio, Virginia and Wisconsin.

3. Plaintiff brings this individual and class action to redress Defendants' repeated violations of ERISA resulting from their practice of denying coverage for two-level cervical artificial disc replacement surgery ("2C-ADR") on the bases it is "investigational" and not "medically necessary." Defendants have developed and used a coverage guideline, the Anthem "Medical Policy" on "Cervical Total Disc Arthroplasty," Policy No. SURG.00055 (hereinafter "SURG.00055"), that provides 2C-ADR is not safe and effective and excluded as such under all Anthem Plans. Under this guideline, Defendants have erroneously denied all requests for 2C-ADR under an incorrect standard. Contrary to Defendants' position, 2C-ADR is safe and effective, has been approved by the United States Food and Drug Administration ("FDA"), and has been regularly performed by renowned surgeons at leading medical centers across the country.

JURISDICTION AND VENUE

4. This action is brought under 29 U.S.C. §§ 1132(a), (e), (f) and (g) as it involves a claim by Plaintiff for employee benefits under an employee benefit plan regulated and governed by ERISA. Subject matter jurisdiction is predicated under these code sections as well as 28 U.S.C. § 1331 as this action involves a federal question.

5. The Court has personal jurisdiction over Defendants because ERISA provides for nationwide service of process, and each defendant has minimum contacts with the United States. *See* 29 U.S.C. § 1132(e)(2).

6. The claims of Plaintiff and the putative class arise out of policies Defendants issued, administered, and/or implemented in this District. Thus, venue is proper in this judicial district pursuant to 29 U.S.C. § 1132(e)(2) (setting forth special venue rules applicable to ERISA actions).

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THE PARTIES

7. Plaintiff was at all relevant times covered under the Motion Picture Industry Health Plans ("MPIHP"), an employee welfare benefit plan regulated by ERISA and pursuant to which Plaintiff is entitled to health care benefits.

8. Anthem and Anthem UM are corporations with their principal place of business in Indianapolis, Indiana. They administer and make benefit determinations related to ERISA health care plans around the country.

9. Defendants do not operate independently and in their own interests, but serve solely to fulfill the purpose, goals and policies of each other.

SUBSTANTIVE ALLEGATIONS

A. Plaintiff's plan

10. At all relevant times, Plaintiff and the class members were covered by health plans, either self-funded or fully insured, administered by Defendants which provided medical and surgical benefits. The health plans set forth the terms and conditions of coverage. Included within the health plans is an exclusion for "investigational" services and a provision requiring that services be "medically necessary."

11. Plaintiff was covered under the MPIHP, a self-insured plan administered by Defendants, as alleged herein. The letter Plaintiff received denying his request for 2C-ADR, and the letter he received denying his appeal, were from Anthem UM who advised that "Anthem UM Services, Inc. provides utilization management services for Anthem Blue Cross and Anthem Blue Cross Life and Health Insurance Company." Anthem Blue Cross and Anthem Blue Cross Life and Health Insurance Company are Anthem's California subsidiaries.

B. 2C-ADR

12. Traditionally, surgeons recommended a spinal fusion to treat degenerative cervical disc disease. Fusion, however, causes a lack of mobility at the

fused disc level and, consequently, more stress on the adjacent disc levels, leading to a greater risk of additional disc herniation/disease.

13. With artificial disc replacement, the diseased disc is replaced with an artificial disc that maintains the integrity of the disc space while providing the flexibility of a natural disc.

14. On August 23, 2013, the FDA granted Pre-Market Approval of the Mob-C device for use in 2C-ADR. The FDA approved this device with the following indicated uses: a patient with "intractable radiculopathy (arm pain and/or neurological deficit) with or without neck pain," confirmation "by radiographic imaging . . . [of] herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height compared to adjacent levels," and "failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms[.]"

15. The Pre-Market Approval process is rigorous and applies to all Class III medical devices. Class III medical devices are devices which, by definition, present significant risks to human health. These devices must therefore meet the FDA's most stringent safety standards before they are approved for commercial sale and distribution. *Riegel v. Medtronic*, *Inc.*, 552 U.S. 312, 317-318, 322-323 (2008).

16. In addition to FDA approval, 2C-ADR has been widely recognized in the medical community and by providers throughout the nation as a viable, safe and effective treatment for cervical disc disease.

C. Defendants' Medical Policies

17. To enable their administration of fully insured and self-insured health plans, Defendants have developed "Medical Policies," that is, written directives on coverage positions they take with respect to certain medical treatments. *Inter alia*, the Medical Policies provide Defendants' coverage position on whether certain treatments are investigational and/or medically necessary.

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18. As stated in Anthem's "Medical Policy Formation" document:

> The Office of Medical Policy & Technology Assessment (OMPTA) develops medical policy and clinical UM guidelines (collectively, "Medical Policy") for the company. The principal component of the process is the review for development of medical necessity and/or investigational policy position statements or clinical indications for certain new medical services and/or procedures or for new uses of existing services and/or procedures.

19. Anthem UM uses the Medical Policies to administer claims under Anthem Plans. Anthem UM participates with Anthem in the development of the Medical Polices and uses the Medical Policies in adjudicating claims. As set forth below, Anthem UM has used SURG.00055 to deny requests for 2C-ADR.

D. Defendants' denials of requests for 2C-ADR

20. Anthem Plans exclude "investigational" services and define that term in substantially the same manner as services:

> 1) that have progressed to limited use on humans, which are not generally accepted as proven and effective procedures within the organized medical community; or 2) that do not have final approval from the appropriate governmental regulatory body; or 3) that are not supported by scientific evidence which permits conclusions concerning the effect of the service, drugs or device on health outcomes; 4) that do not improve the health outcome of the patient treated; or 5) that are not as beneficial as any established alternative; or 6) whose results outside the Investigational setting cannot be demonstrated or duplicated; or 7) that are not generally approved or used by Physicians in the medical community.

21. Anthem Plans also do not cover services that are not "medically necessary" and define that term in substantially the same manner as services that are:

> 1. Appropriate and necessary for the diagnosis or treatment of the medical condition;

> 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease;
>
> . . .
>
> 7. The most appropriate procedure, supply, equipment or service which can safely be provided. The most appropriate procedure, supply, equipment or service must satisfy the following requirements:
>
> a. There must be valid scientific evidence demonstrating that the expected health benefits from the procedure, supply, equipment or service are clinically significant and produce a greater likelihood of benefit, without a disproportionately greater risk of harm or complications, for you with the particular medical condition being treated than other possible alternatives; and
>
> b. Generally accepted forms of treatment that are less invasive have been tried and found to be ineffective or are otherwise unsuitable.

22. Despite the proven safe and effective use of 2C-ADR, Defendants have denied all requests for the surgery on the bases it is investigational and not medically necessary in all circumstances. Defendants have used SURG.00055 to deny requests for the surgery. That Medical Policy stated in relevant part:

> Cervical total disc arthroplasty at more than one spinal level is considered **investigational and not medically necessary** for all indications.

(SURG.00055, effective August 10, 2015, p. 2, emphasis in original.)

23. In stating that 2C-ADR is not covered "for all indications," the Medical Policy mandated that 2C-ADR was not covered regardless of the claimant's medical profile or diagnosis.

24. Pursuant to SURG.00055, Defendants have denied all requests for 2C-ADR as investigational and not medically necessary "for all indications."

25. Because Defendants categorically denied all requests for 2C-ADR as investigational and not medically necessary, they did not develop any medical criteria

similar to the FDA's indicated uses on the Mobi-C device for when Defendants would approve a particular member's request for 2C-ADR. Hence, Defendants conducted no medical eligibility analysis for any person requesting 2C-ADR and denied all such requests under an erroneous standard.

26. In August of 2016, Defendants admitted the erroneous nature of their 2C-ADR position by changing their Medical Policy to cover the procedure. Despite this reversal, Defendants have taken no action to reevaluate or reprocess their prior denials made under the erroneous investigational and not medically necessary denial bases.

E. Defendants deny Plaintiff's request for 2C-ADR

27. Plaintiff suffered from severe neck pain that radiated into his right arm.

28. Plaintiff saw his primary care physician, Dr. Steven Ando, for his neck condition. Plaintiff received conservative treatment, including oral analgesics and an epidural injection.

29. In November of 2014 Dr. Ando referred Plaintiff to a board-certified neurosurgeon, Nouzhan Sehati, M.D., for evaluation. An MRI was performed that showed severe degenerative changes at disc levels C5-C6 and C6-C7. Dr. Sehati recommended that Plaintiff continue with conservative treatment to see if Plaintiff's condition would improve.

30. In September of 2015 Plaintiff returned to see Dr. Sehati due to a worsening of his condition. Despite undergoing physical therapy, home exercises, high dose analgesics, and five more epidural injections, Plaintiff's neck pain and radiating pain were preventing him from performing his activities of daily living. Given Plaintiff's age, 42, Dr. Sehati recommended that Plaintiff undergo 2C-ADR.

31. Dr. Sehati then sought authorization from Defendants for the performance of a 2C-ADR on Plaintiff.

32. On September 29, 2015 Anthem UM sent Plaintiff a letter advising that "Anthem UM Services, Inc. provides utilization management services for Anthem

Blue Cross and Anthem Blue Cross Life and Health Insurance Company." Anthem UM stated:

> Coverage for the requested service is denied because the service does not meet the criteria for "medical necessity" under your description of benefits. Services which are not considered medically necessary are not covered under your description of benefits.

33. Anthem UM did not advise Plaintiff which of its medical necessity criteria it was referring to or state the reason his request for 2C-ADR was not medically necessary.

34. Anthem UM's letter further advised Plaintiff that:

> These devices are used to separate the bones in your neck after a disc is removed. Medical studies have not shown that using this device at more than one level in your neck improves health. For this reason we believe that this use is investigational. We based this decision on the health plan medical policy, Cervical Total Disc Arthroplasty (SURG.00055).

35. The foregoing language was form language used by Defendants when denying requests for 2C-ADR.

36. Plaintiff appealed this decision. In response, Anthem UM sent Plaintiff a letter on October 7, 2015 wherein it again advised that "Anthem UM Services, Inc. provides utilization management services for Anthem Blue Cross and Anthem Blue Cross Life and Health Insurance Company." Anthem UM affirmed its prior denial of Plaintiff's request for 2C-ADR as investigational and again stated: "We based this decision on the health plan medical policy, Cervical Total Disc Arthroplasty (SURG.00055)."

37. Plaintiff made subsequent requests to Defendants and to MPIHP demanding that Anthem UM's denial be reversed given his need for the surgery, the various studies supporting the use of 2C-ADR, the FDA approval of the surgery, and the acceptance of the surgery in the medical community as safe and effective.

38. On April 29, 2016, MPIHP advised Plaintiff that it was rejecting his request for 2C-ADR based upon "Anthem's reviews and denials, and three

independent board certified reviews." One of those reviews concluded that 2C-ADR was *not* investigational. The other two reviews relied on Anthem's Medical Policy for Cervical Total Disc Arthroplasty.

39. Because it was Defendants' policy and practice to deny coverage for 2C-ADR "for all indications," Defendants did not assess whether Plaintiff met any individual medical criteria for receiving 2C-ADR. Defendants simply determined that Plaintiff was requesting 2C-ADR and applied the coverage position in their Medical Policy without an evaluation of whether Plaintiff met any medical criteria for 2C-ADR.

40. After Defendants changed their Medical Policy in August of 2016 they did not contact Plaintiff to advise that he could have his prior denial of 2C-ADR reevaluated and reprocessed under new medical criteria.

CLASS ACTION ALLEGATIONS

41. Plaintiff brings this action on behalf of himself and all others similarly situated as a Class Action pursuant to Federal Rules of Civil Procedure Rule 23. Pursuant to Rule 23(b)(1) and (b)(2), Plaintiff seeks certification of a class defined as follows:

> All persons covered under Anthem Plans, governed by ERISA, self-funded or fully insured, whose requests for two-level cervical artificial disc replacement surgery were denied by Anthem UM at any time from August 24, 2013 pursuant to Anthem's Medical Policy on Cervical Total Disc Arthroplasty, SURG.00055, on the bases the surgery was "investigational and not medically necessary for all indications."

42. Plaintiff and the Class reserve the right under Federal Rule of Civil Procedure Rule 23(c)(l)(C) to amend or modify the class to include greater specificity, by further division into subclasses, or by limitation to particular issues.

43. This action has been brought and may be properly maintained as a class action under the provisions of Federal Rules of Civil Procedure Rule 23 because it meets the requirements of Rule 23(a) and Rule 23(b)1 and (b)(2).

A. Numerosity

44. The potential members of the proposed class as defined are so numerous that joinder of all the members of the proposed class is impracticable. While the precise number of proposed class members has not been determined at this time, Plaintiff is informed and believes that there are a substantial number of individuals covered under Anthem Plans who have been similarly affected.

B. Commonality

45. Common questions of law and fact exist as to all members of the proposed class.

C. Typicality

46. The claims of the named Plaintiff are typical of the claims of the proposed class. Plaintiff and all members of the class are similarly affected by Defendants' wrongful conduct.

D. Adequacy of representation

47. Plaintiff will fairly and adequately represent and protect the interests of the members of the proposed class. Counsel who represent Plaintiff are competent and experienced in litigating large and complex class actions.

E. Superiority of class action

48. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. Individual joinder of all members of the proposed Plaintiff Class is not practicable, and common questions of law and fact exist as to all class members.

49. Class action treatment will allow those similarly situated persons to litigate their claims in the manner that is most efficient and economical for the parties and the judicial system. Plaintiff is unaware of any difficulties that are likely

to be encountered in the management of this action that would preclude its maintenance as a class action.

F. Rule 23(b) requirements

50. Inconsistent or varying adjudications with respect to individual members of the class would establish incompatible standards of conduct for Defendants.

51. Adjudications with respect to individual class members would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests.

52. Defendants have acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole.

FIRST CLAIM FOR RELIEF
DENIAL OF PLAN BENEFITS AND FOR CLARIFICATION OF RIGHTS UNDER AN ERISA PLAN [29 U.S.C. § 1132(a)(1)(B)]

53. Plaintiff and the class members repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as if fully set forth herein.

54. 29 U.S.C. § 1132(a)(1)(B) entitles Plaintiff to recover benefits due and to enforce and clarify her rights to the benefits at issue.

55. As set forth above, Defendants have categorically denied all requests for 2C-ADR based upon the position stated in SURG.00055 that 2C-ADR surgery is investigational and not medically necessary and was so "for all indications."

56. Pursuant to their practice of denying 2C-ADR, Defendants have improperly denied Plaintiff's request and all class members' requests for 2C-ADR surgery on the basis the surgery is investigational and not medically necessary. Defendants have made their denials pursuant to the erroneous SURG.00055 that failed to acknowledge the scientific evidence of the safety and effectiveness of 2C-

ADR, the FDA approval of 2C-ADR, and the surgery's acceptance in the medical community as a safe and effective procedure to treat cervical disc disease.

57. Because of their erroneous across-the-board denial of 2C-ADR, Defendants did not develop medical criteria for the approval of the surgery and did not assess the individual medical eligibility of any person for the surgery.

58. Based on the foregoing, there is now due and owing to Plaintiff benefits, interest, and attorneys' fees in an amount to be determined at the time of trial.

59. On behalf of the class, Plaintiff seeks a clarification of rights relating to Defendants' categorical denial of 2C-ADR as "investigational" and not medically necessary.

SECOND CLAIM FOR RELIEF
BREACH OF FIDUCIARY DUTY AND EQUITABLE RELIEF UNDER AN ERISA PLAN [29 U.S.C. § 1132(a)(3)]

60. Plaintiff and the class members repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as if fully set forth herein.

61. As alleged herein, Defendants have acted as ERISA fiduciaries with respect to the administration and claims decisions under Anthem Plans and, in particular, have acted as ERISA fiduciaries in denying requests for 2C-ADR.

62. Defendants have categorically and improperly denied class members' requests for 2C-ADR surgery, as alleged above.

63. Additionally, Defendants have violated ERISA, 29 U.S.C. § 1133, and its implementing regulations, 29 C.F.R. 2560.503-1. With respect to their "not medically necessary" denial basis, Defendants failed to state in their form letters denying requests for 2C-ADR "the specific reason or reasons for the adverse benefit determination," and failed to provide a "[r]eference to the specific plan provisions on which the determination is based." With respect to their "investigational" denial basis, Defendants

recited no "reason" other than "[m]edical studies have not shown using this device at more than one level in your neck improves health."

64. In acting and failing to act as described above, Defendants have breached their fiduciary duties.

65. Pursuant to 29 U.S.C. § 1132(a)(3), Plaintiff and the class members seek declaratory, equitable and remedial relief as follows:

a. An order that 2C-ADR has not been investigational since the FDA's approval of the Mobi-C device for 2C-ADR on August 23, 2013 and has been medically necessary under appropriate medical criteria since that time;

b. An injunction requiring Defendants to reevaluate and reprocess Plaintiff's and class members' requests for 2C-ADR without the erroneous investigational and not medically necessary denial bases and under appropriate medical criteria;

c. An injunction requiring Defendants to provide notice of the reevaluation and reprocessing in the form and manner required by ERISA to all class members who have had requests for 2C-ADR denied;

d. An injunction preluding Defendants from relying on specific reasons or specific policy provisions not recited in their form denial letters.

e. An accounting of any profits made by Defendants from the monies representing the improperly denied claims and disgorgement of any profits;

f. Such other equitable and remedial relief as the Court may deem appropriate; and

g. Attorneys fees in an amount to be proven.

REQUEST FOR RELIEF

Wherefore, Plaintiff and the class members pray for judgment against Defendants as follows:

1. Benefits denied Plaintiff in an amount to be proven at trial, including interest;

2. A clarification of rights to benefits under the plan for all class members;

3. Injunctive and declaratory relief, as described above;

4. An accounting of any profits made and retained through the improper denial of claims and disgorgement of any profits;

5. Attorneys' fees; and

6. Such other equitable and remedial relief as the Court may deem just and proper.

DATED: July 11, 2017

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